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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,893	09/28/2001	Alessandra D'Azzo	SJ-01-0020	4347

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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/966,893	D'AZZO ET AL.	
	Examiner	Art Unit	
	Christian L Fronda	1652	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *05 September 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☐ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *8-13*.

   Claim(s) withdrawn from consideration: *1-7 and 14-20*.

8. ☒ The drawing correction filed on *9/28/2001* is a)☒ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 2. NOTE: Claims 8-10 are objected to because they recite non-elected subject matter. Applicants are required to cancel the claims or amend the claims to recite the elected subject matter of protectiv protein/cathepsin A (PPCA) and Galactosialidosis. Each of the diseases and enzymes or proteins are patentably distinct and independent and each disease has different etiologies. A search of all the inventions in the patent literature and the non-patent literature cannot be made without serious burden because the inventions require separate searches that have different limits, boundaries, scope, and subject matter.

Claims 8-13 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record as supplement d below as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention since there is no written description provide by the specification that indicates that any lysosomal disease/disorder of any etiology can be treated by any of the recited proteins/enzymes. The specification does not provide a written description of administering any of the recited proteins/enzymes to treat any lysosomal storage disorder given that each of the diseases listed in Table 1 of the specification have different etiologies based on the various enzyme/proteins deficiencies.

Claim 8-13 stand rejected under 35 U.S.C. 112, first paragraph, for the reasons of record as supplemented below because the specification, while being enabling for composition comprising a protective protein/cathepsin A (PPCA) protein useful for treating Galactosialidosis, does not reasonably provide enablement for any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The standard for meeting the enablement requirement is whether one of skill in the art can make or use the invention without undue experimentation. The amount of experimentation to make the claimed composition is enormous and undue and entails determining whether a particular disease is a lysosomal storage disorder disease, determining the etiology of the disease, formulating a composition using PPCA to treat or cure the disease, and determining whether the composition is able to treat or cure the patient without harming the patient.

Since such experimentation is not routine in the art, where the expectation of obtaining any pharmaceutical composition comprising PPCA which can be used to treat any patient having any lysosomal storage disorder is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the a specific composition which is effective in treating a patient having any lysosomal storage disease and in vivo experiments showing that the composition is able to treat or cure the patient without harming the patient. Without such a guidance, the experimentation left to those skilled in the art is undue.

Claims 8-13 stand rejected under 35 U.S.C. 102(a) as being anticipated by Sharp (WO 00/39150) for reasons of record as supplemented below. The Sharp publication has been attached to the previous Office Action. The teachings of Sharp have been stated in the previous Office Action.

The claims do not recite specific post translational modifications or specific structural properties which distinguish the claimed invention from the composition taught by Sharp. Applicant must show an unobvious difference between the claimed invention and the composition taught by Sharp because determination of patentability is based on the product itself and patentability of a product do s not depend on its method of production. Thus, the teachings of Sharp anticipate the claimed invention..